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## Chapter 6 – Office of Criminal Investigations

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## Office of Criminal Investigations

The Office of Criminal Investigations (OCI) cases described below have been successfully prosecuted and have complete judicial actions.

### Center for Biologics Evaluation and Research

#### Health Facility Selling Counterfeit Flu Vaccine

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In October 2005, the Federal Bureau of Investigation (FBI) notified OCI that it had received information that Iyad Abuelhawa, d/b/a Comfort and Caring Home Health, was selling flu vaccine that was possibly counterfeit. It was alleged that Abuelhawa was attending health fairs in the Houston, Texas area, and purportedly administering flu vaccine, of an unknown origin. In addition, it was alleged that Abuelhawa was filling the syringes at his residence.

Just prior to a search of Abuelhawa's home, OCI and FBI agents, in conjunction with investigators from the Texas State Department of Health, observed Abuelhawa dispose 32 syringes into a nearby dumpster after being warned by co-conspirator Denise Gonzales that agents were coming to his house. Gonzales, an employee of a local doctor's office, had participated in the health fairs conducted by Abuelhawa.

FDA's FCC examined some of the syringes that Abuelhawa threw away in the dumpster and determined that the syringes did not contain flu vaccine but instead contained purified water.

On September 6, 2006, in the U.S. District Court for the Southern District of Texas, Iyad Abuelhawa pled guilty to health care fraud violations and misbranding. Abuelhawa was sentenced on April 30, 2007, to 46 months confinement and 36 months supervised release.

Denise Gonzales pled guilty on September 14, 2006, to health care fraud. On May 14, 2007, Gonzales was sentenced to 6 months home confinement and five years supervised release.

## Center for Drug Evaluation and Research

### Illegal Drug Promotion

#### Guilty Plea: Purdue Pleads Guilty to Illegal Promotion, Marketing and Sale of Powerful Rx Pain Medication

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Purdue Agrees to Pay \$700 Million to Resolve Criminal Charges and Civil Liabilities in Connection with Illegal Schemes to Promote OxyContin

On May 10, 2007, OCI announced that Purdue Frederick Company, Inc., (Purdue) agreed to pay more than \$700 million to resolve

criminal charges and civil liabilities in connection with several illegal schemes to promote, market and sell OxyContin, a powerful prescription pain reliever the company produces.

An investigation by OCI uncovered an extensive, long-term conspiracy by Purdue to generate the maximum amount of revenues possible from the sale of OxyContin through various illegal schemes. To further this goal, Purdue trained its sales representatives:

- to make false representations to health care providers about the difficulty of extracting oxycodone, the active ingredient, from the OxyContin tablet;
- to represent to health care providers that OxyContin did not cause euphoria and was less addictive than immediate-release opiates; and
- to allow health care providers to believe that OxyContin was less addictive than morphine.

In addition, Purdue falsely labeled OxyContin as providing "fewer peaks and valleys than with immediate-release oxycodone" and representing that "...delayed absorption as provided by OxyContin Tablets is believed to reduce the abuse liability of the drug."

To resolve the criminal charges, Purdue pled guilty to a felony count of misbranding a drug with intent to defraud and mislead. As part of the plea, Purdue will pay a \$600 million settlement. That amount includes a criminal fine, restitution to government agencies, and over \$276 million in forfeiture. In a separate civil settlement, Purdue will pay \$100.6 million to the United States.

In addition, Purdue's current and former executive employees, Michael

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Friedman, Howard Udell and Dr. Paul Goldenheim, pled guilty to a misdemeanor violation of misbranding OxyContin by illegally promoting the drug as being less addictive, less subject to abuse, and less likely to cause tolerance and withdrawal than other pain medications.

This case was prosecuted by the U. S. Attorney's Office for the Western District of Virginia and investigated by FDA's OCI, the Internal Revenue Service's Criminal Investigations Division, the U.S. Department of Health and Human Services' Office of Inspector General, and the State Police Departments of Virginia and West Virginia. This case serves as an excellent example of federal and state law enforcement cooperation.

### **Counterfeit Drugs Sold Over the Internet**

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During an OCI investigation involving counterfeit drugs, Niaja Kane of Philadelphia, Pennsylvania, was identified as a purchaser and distributor of counterfeit medications from a manufacturer in China. Kane sent samples of medications to a counterfeit pharmaceutical manufacturer in China to be made on her behalf.

After the counterfeit medications were made, they were then shipped back to Niaja Kane in Philadelphia, for eventual sale on the Internet and other venues. During a search of Kane's home, OCI agents found more than 8,900 counterfeit Percocet tablets, 2,040 counterfeit Viagra tablets, and 1,200 fake Cialis tablets among others.

Kane was convicted in U.S. District Court for the Eastern District of Pennsylvania, for trafficking in counterfeit goods and controlled substance charges. On January 22, 2007, Kane was sentenced to 32 months incarceration and 2 years probation.

This OCI case was investigated with the assistance of U.S. Immigration and Customs Enforcement (ICE) and the U.S. Postal Inspection Service.

### **Nitrous Oxide Sold for Recreational Use**

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In July 2004, OCI was notified by the U.S. Attorney's Office, Eastern District of Michigan, that federal drug agents had executed searches of an after hours party

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at a bar in Wyandotte, Michigan. At the time of the search, three large nitrous oxide cylinders were seized.

OCI's investigation identified Adolf Veshtaj as the supplier of the nitrous oxide cylinders. Three other Detroit area compressed gas distributors were also identified as having sold nitrous oxide and sulfur cylinders to Adolf Veshtaj and his company, Suburban Specialty Gases, Inc.

OCI's investigation determined that over a six year period, Adolf Veshtaj purchased over 3,377 cylinders and then sold them for substantial profit. During a search of Adolf Veshtaj's residence and his rented storage facility, over 40 nitrous oxide cylinders were recovered, in addition to stolen identity documents and automatic weapons. The documents were turned over to the United States Secret Service who learned that Adolf Veshtaj was also involved in identity theft, credit card fraud, and bank fraud. The firearms were turned over to the Bureau of Alcohol, Tobacco and Firearms (ATF).

Adolf Veshtaj appeared in the Eastern District of Michigan and pled guilty to credit card fraud, misbranding and adulteration charges for improperly labeling the nitrous oxide and sulfur cylinders knowing that they would ultimately be used for human inhalation and intoxication.

On March 20, 2007, Adolf Veshtaj was sentenced to 12 months and one day incarceration and ordered to make restitution in the amount of \$19,770 to the banking institutions for the credit card fraud. He was also ordered to pay \$200,000 in taxes and interest penalty payments to the Internal Revenue Service.

### **Investigation Discloses Nurse Tampering with Fentanyl**

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This joint OCI, Drug Enforcement Administration, and Valparaiso Police Department (Valparaiso, Indiana) case involved the tampering of Fentanyl syringes by a nurse, Nanette Eichenberger, who was working at a pain relief center located in Valparaiso, Indiana.

During the investigation, OCI recovered four suspect syringes. The syringes were subsequently sent to FDA's Forensic Chemistry Center (FCC) for analysis. FCC determined that none of the syringes tested positive for Fentanyl, but in fact, tested positive for saline solution.

Eichenberger later admitted to stealing the Fentanyl from the syringes for her personal use and replacing the syringes with saline solution.

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On January 26, 2007, Eichenberger pled guilty in the Northern District of Indiana to knowingly and intentionally obtaining a scheduled II controlled substance (Fentanyl) by fraud and deception. Eichenberger was sentenced on April 26, 2007, to one year probation and a \$500 fine.

### **Firm Giving Unapproved Botox Treatments**

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In November 2004, the CDC notified FDA that four individuals had been hospitalized after receiving an unapproved botulinum toxin type A treatment. The botulinum toxin type A was manufactured by Toxin Research International (TRI), an Arizona firm. OCI initiated investigations throughout the United States to investigate the purchase and use of this unapproved and potentially harmful product.

Dr. Hugh Hetherington, a Bozeman, Montana physician, was identified as having purchased quantities of the unapproved product, which was labeled, "For research purposes only, not for human use." Hetherington told his patients that the TRI product was a generic version of the FDA approved Botox, manufactured by Allergan. Hetherington charged less to those patients who unknowingly chose the unapproved TRI product than those who opted for the more expensive approved Botox.

Dr. Hetherington was convicted in the U.S. District Court , District of Montana, for introducing a misbranded drug into interstate commerce. On December 12, 2006, Hetherington was sentenced to two years probation, fined \$5,000, and ordered to pay restitution to those patients who received the unapproved drug.

As part of the investigation into the unapproved TRI product, Jerome Lentini was identified as another physician who had purchased the unapproved botulinum toxin type A product from Toxin Research International. Lentini, a Tigard, Oregon physician, injected hundreds of his patients with the unapproved TRI product. Cathy Garcia, Lentini's nurse, ordered the TRI product and personally injected patients with the product. Lentini and Garcia led their patients to believe that they were receiving the approved botulinum toxin type A Botox manufactured by Allergan. During this investigation, federal investigators discovered that Lentini was also using an unapproved botulinum toxin which he had purchased from China. The investigation also disclosed that Lentini and Garcia collected fees of approximately \$330,000 in connection with these treatments.

Lentini was convicted in the U.S. District Court for the District of Oregon of a felony count of misbranding a drug with intent to mislead. Garcia was convicted of a misdemeanor count for misbranding a drug while held for sale.

On August 14, 2006, Garcia was sentenced to 12 months confinement and ordered to pay \$330,000 in restitution. She also surrendered her nursing license.

On December 11, 2006, Lentini was sentenced to 18 months confinement and ordered to pay \$330,000 in restitution. He also surrendered his license to practice medicine. This case was investigated with the assistance of the Federal Bureau of Investigation.

### **Couple Guilty of Product Tampering**

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On January 29, 2006, OCI received information that William Cunningham and his wife took their three-year-old son and 18 month-old daughter to an urgent care facility in Henry County, Georgia, when they became ill after consuming Campbell's Chicken Noodle Soup at their residence in Stockbridge, Georgia. Due to their daughter's severe condition, she was helicopter-transported to the Children's Healthcare Hospital of Atlanta. Cunningham's son was transported to the same hospital via ambulance where both siblings were admitted and later released. The Cunninghams brought the suspect can of Campbell's Soup to the hospital where the microbiology department retained a sample of the soup for analysis.

During this investigation, investigators discovered that on two other occasions, William Cunningham reported to the Campbell Soup Company and USDA Food Safety Inspection Service that his children became ill after consuming Campbell's canned foods. During one of these incidents, it was reported that a nurse at the hospital commented that the soup smelled like lighter fluid.

During a search of the Cunningham's residence, two partially filled cans of lighter fluid, along with empty and unopened Campbell's food products were seized. The evidence found in the Cunningham's home, and the sample of soup taken by Children's Healthcare Hospital, were sent to FDA's Forensic Chemistry Center for analysis. The investigation disclosed that the soup sample taken by the hospital contained the drug Amitriptyline, an anti-depressant commonly found in Tryptonol, and the drug Fluoxetine, an anti-depressant commonly found in the drug Prozac.

On February 6, 2007, William Cunningham pled guilty in the Northern District of Georgia to falsely reporting a product tampering. He was sentenced to 60 months incarceration and three years of supervised release. He was also ordered to have no contact with the children during his sentence and supervised release.

### **Distribution of Controlled Substance**

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This OCI case was a joint investigation with the U.S. Drug Enforcement Administration (DEA), U.S. Postal Inspection Service, and the Nebraska State Police. The investigation began in December 2004, when OCI received information that Vladimir Ribartchouk, a New York City resident, was filling prescription drug orders over the Internet. The investigation revealed that Ribartchouk received cash payments for orders of a variety of medications including human growth hormone (HGH), Deca-Durobolin, Cialis, tamoxifen, and thyroid medications. In order to facilitate this large scale international operation, Ribartchouk used various fictitious names and addresses, numerous post office boxes, and used several drug suppliers in Texas, California, and England.

As this investigation progressed, a joint federal and Nebraska state case obtained enough evidence to charge Ribartchouk in the State of Nebraska for distribution of controlled substances.

On July 27, 2005, Ribartchouk was arrested by OCI, DEA, and Postal Inspectors in New York City, and extradited to Nebraska to face drug distribution charges. On December 8, 2005, Ribartchouk was sentenced to one and one-half to two years incarceration in Lancaster County, Nebraska.

After Ribartchouk completed his prison sentence in Nebraska, he was released into federal custody and extradited to New York to face federal charges for selling medications on the Internet. He pled guilty to controlled substance violations and on February 15, 2007, he was sentenced to 12 months and one day incarceration.

### **Joint Investigation Finds "Doctor" Not Licensed to Practice**

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In 2003, OCI initiated an investigation with the Federal Bureau of Investigation, (FBI) the Health and Human Services Office of Inspector General, (OIG) and the Connecticut Office of the Chief State's Attorney - Medicaid Fraud Control Unit.

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This investigation involved an allegation that between 1996 to 2003, Dr. Juan Fica employed an individual named Eli Nakouzi to work at his Waterbury, Connecticut medical practice. Although Nakouzi was not licensed to practice medicine, Nakouzi, at Dr. Fica's direction, treated patients, prescribed medicines, and was referred to as "Doctor Nakouzi." Fica then billed Medicaid and private health insurance companies for services rendered by Nakouzi representing them as services rendered by Dr. Fica. Through this scheme, Dr. Fica defrauded government and private health insurance companies in excess of \$156,000.

Dr. Fica was convicted in U.S. District Court, New Haven, Connecticut, for conspiracy and health care fraud. On August 9, 2006, he was sentenced to 18 months confinement and two years of supervised release. He was also ordered to pay a \$4,000 fine and to pay restitution in the amount of \$155,906 to Medicaid and the private health insurance companies.

Nakouzi was convicted in U.S. District Court, New Haven, Connecticut, for conspiracy and health care fraud. On December 13, 2006, he was sentenced to two months confinement, four months home confinement, and three years of supervised release. He was also ordered to pay a \$4,000 fine and perform 150 hours of community service.

## **Center for Devices and Radiological Health**

### **Radiological Technologist Falsifies Documents in Mammography Images and Documents**

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This case began in February 2005, when Geisinger Medical Group reported to the Pennsylvania Department of Environmental Protection (DEP) that Josephine Latini, a radiological technologist, routinely produced false images and falsified documents required by the Mammography Quality Standards Act (MQSA) at Lock Haven, Pennsylvania clinic. Geisinger was not aware of the falsification until another employee notified company management.

FDA subsequently requested an Additional Mammography Review (AMR) of the Lock Haven clinic mammograms. The AMR revealed problems with mammographies performed at the Lock Haven clinic. These "problems" were determined to pose a "significant risk" to public health. As a result, accreditation of the Geisinger Lock Haven clinic was revoked.

On February 28, 2006, Geisinger was fined \$900,000 by the Pennsylvania Department of Environmental Protection for violating the MQSA.

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Josephine Latini was convicted in U.S. District Court, Middle District of Pennsylvania, of false statements regarding health care matters. On December 5, 2006, Latini was sentenced to three years probation and ordered to perform 577 hours of community service. Josephine Latini was also ordered to pay restitution in the amount of \$21,872.

## **Center for Food Safety and Applied Nutrition**

### **Antibiotics Dumped into 2,500 Gallons Milk**

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This case began when the New York State Police reported to FDA that antibiotics were dumped into tanks containing 2,500 gallons of raw milk at a farm in Ogden, New York.

A joint OCI, New York State Police, and Ogden Police Department investigation determined that Gerald Fredo, an employee at the Ogden farm, mistakenly combined milk taken from a cow receiving antibiotics with fresh milk, resulting in the adulteration of all of the milk in the two bulk storage tanks. Before the shipment was completed and shipped from the farm, the defendant realized the adulterated milk had been mixed with fresh milk and he stopped the shipment. Thus, at no time was the adulterated milk sold to consumers.

However, to cover-up his mistake, Fredo made false reports to law enforcement. Specifically, Fredo advised law enforcement that he observed a dark colored motor vehicle leaving the milk tank area and reported other suspicious activity at the farm. After extensive investigation, it was determined that Fredo's statements were false.

Fredo pled guilty in the Western District of New York to causing an unadulterated food to be introduced into interstate commerce. He was sentenced on March 13, 2007, to two years of probation. Additionally, Fredo was ordered to make restitution to the Ogden Police Department and the New York State Police Department in the amount of \$2,063.60.

## Center for Veterinary Medicine

### Human Rx Drugs Sold to Race Horse Owners

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OCI initiated this investigation based upon information from the FBI who reported that Joseph McMahon, a Canadian citizen, was offering to sell the human prescription drug Aranesp to harness race horse owners on two different horse racing-related Internet websites. Aranesp is prescribed to treat anemia in humans undergoing chemotherapy or who have kidney disease that results in anemia. It is purported to help horses' stamina during physical exertion.

An OCI agent purporting to be the owner of several race horses, began an online business relationship with McMahon. McMahon sold the OCI agent a quantity of the medication and agreed to meet in person to deliver more Aranesp, agreeing to travel from his residence in Missouri to Kentucky to deliver more of the drug. At this meeting, McMahon sold more Aranesp to the OCI agent along with amounts of Viagra, OxyContin, and Levitra. After the sale, McMahon was arrested by OCI and FBI agents.

McMahon was convicted in the Northern District of Kentucky of violating the Federal Food, Drug, and Cosmetic Act. On December 7, 2006, he was sentenced to eight months confinement and three years probation. Because McMahon is a Canadian citizen, he faces deportation upon his release from incarceration.

OCI conducted an investigation into the sale and distribution of misbranded and unapproved veterinarian drugs by Equirace Health and Speed Products, a Philadelphia, Pennsylvania firm. Marvin Goldberg, the owner of Equirace, dispensed prescription veterinary drugs to people without valid prescriptions; some that he had smuggled into the United States from Canada. Although Equirace was not a registered drug distributor, Equirace was issuing price lists to customers of various prescription injectable drugs used to enhance performance in race horses.

During a search of Goldberg's residence, which also served as his business establishment, investigators found \$40,000 worth of prescription injectable drugs along with documents evidencing his sale of drugs across the United States. OCI's investigation revealed that Goldberg paid a licensed veterinarian, who later cooperated with the investigation, \$2,000 per month to use his license to buy veterinary drugs which Goldberg sold through his business.

Goldberg was convicted in the U.S. District Court for the Eastern District of Pennsylvania for mail fraud, wire fraud, and violations of the Federal Food,

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Drug and Cosmetic Act. On January 4, 2007, Goldberg was sentenced to 57 months confinement, three years of probation thereafter, and ordered to pay \$6,500 in fines.

FDA's Philadelphia District Office assisted OCI in this investigation.